NOV 21 2001

RÜSCH
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
FAX (603) 532-8211 or 6108

K010596

510(k) Summary

1. Submitter Name, Address, and Date of Submission.

Miss Karenann J. Brozowski
Group Regulatory Affairs Director
Rüsch International
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-6207
E-Mail: kbrozowski@compuserve.com

Contact: Same as above

2. Name of the Device, Common, Proprietary (if Known), and Classification.

Classification Name: Tracheal/branchial differential ventilation tube

Common Name: Bronchus Blocker

Proprietary Name: Rüsch Bronchus Blocker

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Rüsch Bronchus Blocker is substantially equivalent to the Vitaid Univent.

4. Description of the Device.

The Rüsch Bronchus Blocker 1700 set, sterile, consists of a white tube of 1700 mm and made of WIRUTHANE for surgical interventions with flexible bronchoscopes. The cuff is made of SILKOLATEX® RÜSCH GOLD. The tube is a double lumen with a radiopaque conical tip that has a central opening. The Proximal end has a detachable Luer-lock adaptor with a

stopcock that attaches to the balloon filling system. The balloon capacity is 3.0-5.0 ml and a 3.0 ml syringe is provide in the sterile pouch. This product is made to be used in conjunction a Rusch tracheal tube. When the bronchus blocker is combined with the tracheal tube, it becomes substantially equivalent to the entire product described by the Univent 510(k) (K894337). As a stand alone product it is substantially equivalent to the like portion of the Univent product.

The Bronchus Blocker Set, Sterile made of WIRUTHANE has a cuff of SILKOLATEX® RÜSCH GOLD, Luer-lock connection, sealing cap, radiopaque opaque, graduated and is approximately 1700 mm long. The balloon capacity is 5.0-6.0 ml and a 5.0 ml syringe is provide in the sterile pouch. This product has a 15 mm connector supplied with it. This product is made to be used in conjunction with a Rüsch tracheal tube. When the bronchus blocker is combined with the tracheal tube, it becomes substantially equivalent to the entire product described by the Univent 510(k) (K894337). As a stand alone product it is substantially equivalent to the like portion of the Univent product.

Both products are supplied with an appropriately sized syringe for filling the balloon. Both products are made of Wiruthan® and Silkolatex®.

5. Intended Use of the Device.
The Bronchus Blocker is a device used to isolate the left of the right lung of a patient for surgery, one lung ventilation, or one lung anesthesia.

6. Summary of Technological Characteristics.

The Rüsch Bronchus Blocker is substantially equivalent in design, use and materials to the noted predicate product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2001

Ms. Karenann J. Brozowski
Rüsch International
Tall Pines Park
Jaffrey, NH 03452

Re: K010596
Rüsch Bronchus Blocker
Regulation Number: 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: II (two)
Product Code: 73 CBI
Dated: September 27, 2001
Received: October 1, 2001

Dear Ms. Brozowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

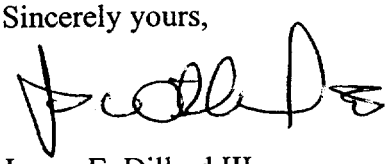
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 21 2001

510(k) Number (if known): K010596

Device Name: Rüsch Bronchus Blocker

Indications for Use:

The Bronchus Blocker is a device used to isolate the left or the right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010596